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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 11

Complete if Known	
Application Number	10/580,746-Conf. #9342
Filing Date	May 26, 2006
First Named Inventor	Ingmar Hoerr
Art Unit	1636
Examiner Name	M. Marvich
Attorney Docket Number	22122-00006-US1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-3,906,092	09-16-1975	Hilleman et al.	
	AB*	US-4,373,071	02-08-1983	Itakura	
	AC*	US-4,401,796	08-30-1983	Itakura	
	AD*	US-4,415,732	11-15-1983	Caruthers et al.	
	AE*	US-4,458,066	07-03-1984	Caruthers et al.	
	AF*	US-4,500,707	02-19-1985	Caruthers et al.	
	AG*	US-4,668,777	05-26-1987	Caruthers et al.	
	AH*	US-4,973,679	11-27-1990	Caruthers et al.	
	AI*	US-5,047,524	09-10-1991	Andrus et al.	
	AJ*	US-5,132,418	07-21-1992	Caruthers et al.	
	AK*	US-5,153,319	10-06-1992	Caruthers et al.	
	AL*	US-5,262,530	11-16-1993	Andrus et al.	
	AM*	US-5,580,859	12-03-1996	Felgner et al.	
	AN*	US-5,663,153	09-02-1997	Hutcherson et al.	
	AO*	US-5,700,642	12-23-1997	Monforte et al.	
	AP*	US-5,965,720	10-12-1999	Gryaznov et al.	
	AQ*	US-6,214,804-B1	04-10-2001	Felgner et al.	
	AR*	US-6,239,116-B1	05-29-2001	Krieg et al.	
	AS*	US-6,265,387-B1	07-24-2001	Wolff et al.	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	BA	WO-93/14778-A1	08-05-1993	Vical Inc		
	BB	WO-97/41210-A1	11-06-1997	Univ Duke et al.		
	BC	WO-98/55495-A2	12-10-1998	Dynavax Tech Corp et al.		
	BD	WO-99/20774-A2	04-29-1999	Genzyme Transgenics Corp		
	BE	EP-1 083 232-A1	03-14-2001	Jung Guenther Prof Dr et al.		
	BF	WO-00/29561-A2	05-25-2000	Statens Seruminstitut et al.		

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	AT*	US-6,322,967-B1	11-27-2001	Parkin	
	AU*	US-6,406,705-B1	06-18-2002	Davis et al.	
	AV*	US-20020132788-A1	09-19-2002	Lewis et al.	
	AW*	US-6,500,919-B1	12-31-2002	Adema et al.	
	AX*	US-6,514,948-B1	02-04-2003	Raz et al.	
	AY*	US-6,552,006-B2	04-22-2003	Raz et al.	
	AZ*	US-6,589,940-B1	07-08-2003	Raz et al.	
	AA1*	US-20030143204-A1	07-31-2003	Lewis et al.	
	AB1*	US-6,610,661-B1	08-26-2003	Carson et al.	
	AC1*	US-20030170273-A1	09-11-2003	O'Hagan et al.	
	AD1*	US-20030225016-A1	12-04-2003	Fearon et al.	
	AE1*	US-6,664,066-B2	12-16-2003	Parks	
	AF1*	US-20040005667-A1	01-08-2004	Ratti et al.	
	AG1*	US-20040106567-A1	06-03-2004	Hagstrom et al.	
	AH1*	US-20050250723-A1	11-10-2005	Hoerr et al.	
	AI1*	US-20050032730-A1	02-10-2005	Von Der Mulbe et al.	
	AJ1*	US-20050037494-A1	02-17-2005	Hecker et al.	
	AK1*	US-20050059624-A1	03-17-2005	Hoerr et al.	See BH
	AL1*	US-20050064596-A1	03-24-2005	Riemen et al.	

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	BG	WO-03/028656-A2	04-10-2003	Chiron Corp et al.		
	BH	WO-03/051401-A2	06-26-2003	Curevac Gmbh et al.	See AK1	
	BI	WO-03/059381-A2	07-24-2003	Curevac Gmbh et al.		
	BJ	WO-03/066649-A1	08-14-2003	Biomira Inc et al.		
	BK	EP-1 393 745-A1	03-03-2004	Hybridon Inc		
	BL	WO-2004/058159-A2	07-15-2004	Dynavax Tech Corp et al.		

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Sheet 3 of 11

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Application Number	10/580,746-Conf. #9342
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First Named Inventor	Ingmar Hoerr
Art Unit	1636
Examiner Name	M. Marvich
Attorney Docket Number	22122-00006-US1

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	AM1*	US-7,001,890-B1	02-21-2006	Wagner et al.	
	AN1*	US-20060172966-A1	08-03-2006	Lipford et al.	
	AO1*	US-2006/0188490-A1	08-24-2006	Hoerr et al.	
	AP1*	US-20060241076-A1	10-26-2006	Uhlmann et al.	
	AQ1*	US-7,208,478-B2	04-24-2007	Carson et al.	
	AR1*	US-7,276,489-B1	10-02-2007	Agrawal et al.	

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	BM	WO-2007/024708-A2	03-01-2007	Univ Pennsylvania et al.		

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First Named Inventor	Ingmar Hoerr
Art Unit	1636
Examiner Name	M. Marvich
Attorney Docket Number	22122-00006-US1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CA	O'DOHERTY, U., et al., Human blood contains two subsets of dendritic cells, one immunologically mature and the other immature. *Immunology* **82** (1994), 487-493.	
	CB	TEUFEL, R., et al., Human peripheral blood mononuclear cells transfected with messenger RNA stimulate antigen-specific cytotoxic T-lymphocytes in vitro. *Cell. Mol. Life Sci.* **62** (2005), 1755-1762.	
	CC	ROMANI, N., et al., Generation of mature dendritic cells from human blood - An improved method with special regard to clinical applicability. *Journal of Immunological Methods* **196** (1996, 137-151.	
	CD	MORSE, M., et al., Generation of dendritic cells *in vitro* from peripheral blood mononuclear cells with granulocyte0macrophage-colony-stimulating factor, interleukin-4, and tumor necrosis factor-α for use in cancer immunotherapy. *Annals of Surgery* **226(1)** (1997), 6-16.	
	CE	FEARNLEY, D.B., et al., Monitoring Human Blood Dendritic Cell Numbers in Normal Individuals and in Stem Cell Transplantation. *Blood* **93(2)** (1999, 728-736.	
	CF	SIENA, S., et al., Expansion of Immunostimulatory Dendritic Cells from Peripheral Blood of Patients with Cancer. *The Oncologist* **2** (1997), 65-69.	
	CG	SALLUSTO, F., et al., Efficient Presentation of Soluble Antigen by Cultured Human Dendritic Cells is Maintained by Granulocyte/Macrophage Colony-stimulating Factor plus Interleukin 4 and Downregulated by Tumor Necrosis Factor α. *J. Exp. Med.* **179** (1994), 1109-1118.	
	CH	WEISSMAN, D., et al., Dendritic Cells Express and Use Multiple HIV Coreceptors. *Dendritic Cells in Fundamental and Clinical Immunology,* Ricciardi-Castagnoli (Ed.), Plenum Press, New York (1997), 401-406.	
	CI	HEISER, A., et al., Autologous dendritic cells transfected with prostate-specific antigen RNA stimulate CTL responses against metastatic prostate tumors. *The Journal of Clinical Investigation* **109(3)** (2002), 409-417.	
	CJ	HEISER, A., et al., Human Dendritic Cells Transfected with RNA Encoding Prostate-Specific Antigen Stimulate Prostate-Specific CTL Responses in Vitro. *The Journal of Immunology* (2000), 5508-5514.	

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(Use as many sheets as necessary)				Art Unit	1636
				Examiner Name	M. Marvich
Sheet	5	of	11	Attorney Docket Number	22122-00006-US1

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	CK	HOLMES, D., et al., Cell Positioning and Sorting using Dielectrophoresis. *European Cells and Materials* **4(Suppl. 2)** (2002), 120-122.	
	CL	ZHANG, X. et al., Advances in Dendritic Cell-Based Vaccine of Cancer. *Cancer Biotherapy and Radiopharmaceuticals* **17(6)** (2002), 601-619.	
	CM	SU, Z. et al., Enhanced Induction of Telomerase-specific CD4+ T Cells Using Dendritic Cells Transfected with RNA Encoding a Chimeric Gene Product. *Cancer Research* **62** (2002), 5041-5048.	
	CN	WEISSMAN, D., et al., HIV GAG mRNA Transfection of Dendritic Cells (DC) Delivers Encoded Antigen to MHC Class I and II Molecules, Causes DC Maturation, and Induces a Potent Human In Vitro Primary Immune Response. *The Journal of Immunology* **165** (2000), 4710-4717.	
	CO	HEISER, A., et al., Induction of Polyclonal Prostate Cancer-Specific CTL Using Dendritic Cells Transfected with Amplified Tumor RNA. *The Journal of Immunology* **166** (2001), 2953-2960.	
	CP	CONRY, R.M. et al., Characterization of a messenger RNA Polynucleotide Vaccine Vector. *Cancer Research* **55** (1995), 1397-1400.	
	CQ	HOERR, I., *In vivo* application of RNA leads to induction of specific cytotoxic T lymphocytes and antibodies. *Eur. J. Immunol.* **30** (2000), 1-7.	
	CR	BOCZKOWSKI, D., et al., Induction of Tumor Immunity and Cytotoxic T Lymphocyte Responses Using Dendritic Cells Transfected with Messenger RNA Amplified from Tumor Cells. *Cancer Research* **60** (2000), 1028-1034.	
	CS	DURET, L. et al., Expression pattern and, surprisingly, gene length shape codon usage in *Caenorhabditis, Drosophila,* and *Arabidopsis. Proc. Nat. Acad. Sci. USA* **96** (1999), 4482-4487.	
	CT	WU, L. et al., Fusion protein vectors to increase protein production and evaluate the immunogenicity of genetic vaccines. *Mol. Ther.* **2(3)** (2000), 288-297. (ABSTRACT ONLY)	

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	CU	HAAS, J. et al., Codon usage limitation in the expression of HIV-1 envelope glycoprotein. *Current Biology* **6(3)** (1996), 315-324.	
	CV	KOIDE, Y. et al., Review - Current Perspective - DNA Vaccines. *Jpn. J. Pharmacol.* **83** (2000), 167-174.	
	CW	NAGATA, T. et al., Codon Optimization Effect on Translational Efficiency of DNA Vaccine in Mammalian Cells: Analysis of Plasmid DNA encoding a CTL Epitope Derived from Microorganisms. *Biochemical and Biophysical Research Communications* **261** (1999), 445-451.	
	CX	KIM, C. et al., Codon optimization for high-level expression of human erythropoietin (EPO) in mammalian cells. *Gene* **199** (1997), 293-301.	
	CY	KOMAR, A.A. et al., Synonymous codon substitutions affect ribosome traffic and protein folding during in vitro translation. *FEBS Letters* **462** (1999), 387-391.	
	CZ	ROBINSON, F. et al., Expression of Human nPTB is Limited by Extreme Suboptimal Codon Content. *PLoS ONE* **3**(3) (2008): e1801, doi: 10.1371/journal.pone.0001801.	
	CA1	PESOLE, G. et al., UTRdb and UTRsite: specialized databases of sequences and functional elements of 5' and 3' untranslated regions of eukaryotic mRNAs. Update 2002. *Nucleic Acids Research* **30(1)** (2002), 335-340.	
	CB1	DUNHAM, S.P., The application of nucleic acid vaccines in veterinary medicine. *Research in Veterinary Science* **73** (2002), 9-16.	
	CC1	LEITNER, W.W. et al., DNA and RNA-based vaccines: principles, progress and prospects. *Vaccine* **18** (2000), 765-777.	
	CD1	LUO, D. et al., Synthetic DNA delivery system. *Nature Biotechnology* **18** (2000), 33-37.	

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	CE1	VERMA, I.M. et al., Gene therapy - promises, problems and prospects. *Nature* **389**, 239-242.	
	CF1	EDELSTEIN, M.L. et al., Gene therapy clinical trials worldwide 1989-2004 - an overview. *J. Gene Med.* **6** (2004), 597-602.	
	CG1	PALU, G. et al., In pursuit of new developments for gene therapy of human diseases. *Journal of Biotechnology* **68** (1999), 1-13.	
	CH1	KUDIA, G. et al., High Guanine and Cytosine Content Increases mRNA Levels in Mammalian Cells. *PLoS Biol* **4(6)** (2006): e180. DOI: 10.1371/journal.pbio.0040180.	
	CI1	WILUSZ, C.J. et al., Bringing the role of mRNA decay in the control of gene expression into focus. *TRENDS in Genetics* **20(10)** (2004), 491-497.	
	CJ1	TOURRIERE, H. et al., mRNA degradation machines in eukaryotic cells. *Biochimie* **84** (2002), 821-837.	
	CK1	MITCHELL, P. et al., mRNA turnover. *Current Opinion in Cell Biology* **13** (2001), 320-325.	
	CL1	ROITT, BROSTOFF AND MALE. Immunology, 4th Edition. Barcelona: Times Mirror International Publishers Limited, 1996, page 1.7.	
	CM1	ROSS, J., Control of messenger RNA stability in higher eukaryotes. *Trends Genet.* **12(5)**:171-5, May 1996.	
	CN1	UEDA, T. et al., Phosphorothioate-containing RNAs show mRNA activity in the prokaryotic translation systems *in vitro*. *Nucleic Acids Research* **19(3)** (1991), 547-552.	

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	CO1	TRINCHIERI, G. et al., Cooperation of Toll-like receptor signals in innate immune defence. *Nature Reviews/Immunology* **7** (2007), 179-190.	
	CP1	RAMAZEILLES, C. et al., Antisense phosphorothioate oligonucleotides: Selective killing of the intracellular parasite *Leishmania amazonensis*. *Proc. Natl. Acad. Sci. USA* **91** (1994), 7859-7863.	
	CQ1	DIEBOLD, S.S. et al., Innate Antiviral Responses by Means of TLR7-Mediated Recognition of Single-Stranded RNA. *Science* **303** (2004), 1529-1531.	
	CR1	HEMMI, H. et al., A Toll-like receptor recognizes bacterial DNA. *Nature* **408** (2000), 740-745.	
	CS1	ZHOU, W.-Z. et al., RNA Melanoma Vaccine: Induction of Antitumor Immunity by Human Glycoprotein 100 mRNA Immunization. *Human Gene Therapy* **10** (1999), 2719-2724.	
	CT1	MATRAY, T.J. et al., Synthesis and properties of RNA analogs - oligoribonucleotide N3'→P5' phosphoramidates. *Nucleic Acids Research* **27(20)** (1999), 3976-3985.	
	CU1	NICHOLSON, A. et al., Accurate *in vitro* cleavage by RNase III of phosphorothioate-substituted RNA processing signals in bacteriophage T7 early mRNA. *Nucleic Acids Research* **16(4)** (1988), 1577-1591.	
	CV1	MINKS, M.A. et al., Structural Requirements of Double-stranded RNA for the Activation of 2',5'-Oligo(a) Polymerase and Protein Kinase of Interferon-treated HeLa Cells. *The Journal of Biological Chemistry* **254(20)** (1979), 10180-10183.	
	CW1	JANSSENS, S. et al., Role of Toll-Like Receptors in Pathogen Recognition. *Clinical Microbiology Reviews* **16(4)** (2003), 637-646.	
	CX1	GRANSTEIN, R.D. et al., Induction of Anti-Tumor Immunity with Epidermal Cells Pulsed with Tumor-Derived RNA or Intradermal Administration of RNA. *J. Invest. Dermatol.* **114** (2000), 632-636.	

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Sheet 9 of 11

Complete if Known	
Application Number	10/580,746-Conf. #9342
Filing Date	May 26, 2006
First Named Inventor	Ingmar Hoerr
Art Unit	1636
Examiner Name	M. Marvich
Attorney Docket Number	22122-00006-US1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CY1	SAENZ-BADILLOS, J. et al., RNA as a tumor vaccine: a review of the literature. *Exp. Dermatol.* **10** (2001), 143-154.	
	CZ1	LOGING, W.T. et al., Identifying Potential Tumor Markers and Antigens by Database Mining and Rapid Expression Screening. *Genome Research* ***10*** (2000), 1393-1402.	
	CA2	WEIDE, B. et al., Results of the first phase I/II clinical vaccination trail with direct injection of mRNA. *J. Immunother.* **31(2)** (2008), 180-188. (Abstract only)	
	CB2	SU, Z. et al., Immunological and Clinical Responses in Metastatic Renal Cancer Patients Vaccinated with Tumor RNA-transfected Dendritic Cells. *Cancer Research* **63** (2003), 2127-2133.	
	CC2	WEIDE, B. et al., Results of the First Phase 1/2 of Clinical Vaccination Trial with Direct Injection of mRNA. *J. Immunother.* **00(00)**, 1-9.	
	CD2	CARRALOT, J-P. et al., Production and characterization of amplified tumor-derived cRNA libraries to be used as vaccines against metastatic melanomas. *Genetic Vaccines and Therapy* **3** (2005), 6.	
	CE2	LENZ, A. et al., Human and Murine Dermis Contain Dendritic Cells. *J. Clin. Invest.* **92** (1993), 2587-2596.	
	CF2	ROSENBERG, S.A. et al., Cancer immunotherapy: moving beyond current vaccines. *Nat Mec.* **10(9)** (2004), 909-915.	
	CG2	HOATH, S.B. et al., The Organization of Human Epidermis: Functional Epidermal Units and Phi Proportionality. *J. Invest. Dermatol.* **121** (2003), 1440-1446.	
	CH2	MEUNIER, L. et al., Heterogeneous Populations of Class II MHC+ Cells in Human Dermal Cell Suspensions. *The Journal of Immunology* **151(8)** (1993), 4067-4080.	

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	CI2	MATHERS, A.R. et al., Professional Antigen-Presenting Cells of the Skin. *Immunologic Research* **36/1-3** (2006), 127-136.	
	CJ2	PALUCKA, A.K. et al., Taming cancer by inducing immunity via dendritic cells. *Immunological Reviews* **220** (2007), 129-150.	
	CK2	LARREGINA, A.T. et al., Changing Paradigms in Cutaneous Immunology: Adapting with Dendritic Cells. *The Journal of Investigative Dermatology* **124** (2005), 1-12.	
	CL2	KARIKO, K. et al., Suppression of RNA Recognition by Toll-like Receptors: The Impact of Nucleoside Modification and the Evolutionary Origin of RNA. *Immunity* **23** (2005), 165-175.	
	CM2	KANDIMALLA, E.R. et al., Divergent synthetic nucleotide motif recognition pattern: design and development of potent immunomodulatory oligodeoxyribonucleotide agents with distinct cytokine induction profiles. *Nucleic Acids Research* **31(9)** (2003), 2393-2400.	
	CN2	KANDIMALLA, E.R. et al., Immunomodulatory oligonucleotides containing a cytosine-phosphate-2'-deoxy-7-deazaguanosine motif as potent Toll-like receptor 9 agonists. *PNAS* **102(19)** (2005), 6925-6930.	
	CO2	LEE, J. et al., Molecular basis for the immunostimulatory activity of guanine nucleoside analogs: Activation of Toll-like receptor 7. *PNAS* **100(11)** (2003), 6646-6651.	
	CP2	AURUP, H. et al., Translation of 2'-modified mRNA *in vitro* and *in vivo*. *Nucleic Acids Research* **22(23)** (1994), 4963-4968.	
	CQ2	DISBROW, G.L., Codon optimization of the HPV-16 E5 gene enhances protein expression. *Virology* **311** (2003), 105-114.	
	CR2	SOUSA, R., Use of T7 RNA Polymerase and Its Mutants for Incorporation of Nucleoside Analogs into RNA. *Methods in Enzymology* **317** (2000), 65-74.	

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	CS2	GAO, X. et al., "Nonviral gene delivery: what we know and what is next." *AAPS J* **9**(1): E92-E104 (2007).	
	CT2	HERWEIJER, H. et al., "Gene therapy progress and prospects: Hydrodynamic gene delivery." *Gene Ther.* **14**(2): 99-107 (2007).	
	CU2	SUDA, T. et al., "Hydrodynamic gene delivery: its principles and applications." *Mol. Ther.* **15**(12): 2063-2069 (2007).	
	CV2	VERMA, I.M. et al., "Gene therapy: twenty-first century medicine." *Annu. Rev. Biochem.* **74**: 711-738 (2005).	
	CW2	WOLFF, J.A. et al., "Direct gene transfer into mouse muscle in vivo." *Science* **247**(4949 Pt. 1): 1465-1468 (1990).	

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